Centers for Medicare & Medicaid Services (CMS) Public Agenda Payment and Coding Determinations for New Durable Medical Equipment

Wednesday, June 30, 2004

CMS Auditorium

7500 Security Boulevard

Baltimore (Woodlawn), Maryland 21244-1850

8:15 a.m. Arrival and sign-in

9:00 a.m. Welcome
Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS's preliminary coding recommendation to the HCPCS National Panel, as well as an overview of Medicare pricing/payment methodology related to the product, is provided in this agenda. Meeting participants will hear presentations about the agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item.

AGENDA ITEM # 1
Attachment #04.82
Request to establish a code for devices providing Static Progressive Stretch ("SPS") Trade Name: Joint Active Systems, Inc. ("JAS").

AGENDA ITEM # 2
Attachment #04.119
Request to establish 3 HCPCS codes for (1) portable overhead lifter, (2) portable track system, and (3) sling, trade name: Guardian Voyager System.

AGENDA ITEM # 3
Attachment #04.122
Request to establish a code for a pneumatic compressor unit and various blanket attachments, that deliver heat, cold and compression to various injury sites trade name: ProThermo.

AGENDA ITEM # 4
Attachment #04.80
Request to establish a code for a pressure redistribution support surface, trade name: Tempur-Med Therapeutic Mattress.

AGENDA ITEM # 5

-Attachment #04.84
Request to establish a code for a chondrogenesis system, Trade Name: BioniCare® Stimulator, Model BIO- 1000™.

-Attachment #04.85
Request to establish a code for replacement supplies for the for BioniCare® Stimulator, Model BIO- 1000™.

-Attachment #04.86
Request to establish a code for a replacement battery for the BioniCare® Stimulator, Model BIO- 1000™.

-Attachment #04.87
Request to establish a code for replacement supplies for a replacement Knee Signal Applicator use with the BioniCare® Stimulator, Model BIO- 1000™.

AGENDA ITEM # 6

Attachment #04.96
Request to establish a code for a radiofrequency signal induction wound closure system, trade name: Provant® Wound Closure System.

AGENDA ITEM # 7

Attachment #04.76
Request to establish a code for a cranial electrotherapy stimulation device, trade name: Alpha-Stim 100 and Alpha-Stim SCS.

AGENDA ITEM # 8

Attachment #04.70
Request for a code for a heated humidification system for ventilatory and respiratory assist applications, trade name: MR850 Heated Humidification System, and codes for the required system parts used in the initial patient set-up and as replacements.

AGENDA ITEM # 9

Attachment #04.77
Request to establish a code for a high flow humidification system, trade name: Vapotherm.

AGENDA ITEM # 10

Attachment #04.72
Request to revise the description of code E0454 to include ventilators providing responsive triggering using other technologies in place of flow triggering, trade name: Newport HT50 Ventilator.

AGENDA ITEM # 11
Attachment #04.92
Request to establish a code for an automatic, self-adjusting sleep apnea breathing therapy device, trade name: AutoSet Spirit™ auto adjusting respiratory device.

AGENDA ITEM # 12
Attachment #04.93
Request to establish a code for an automatic, self-adjusting sleep apnea breathing therapy device, trade name: GoodKnight® 420 Evolution auto adjusting respiratory device.

AGENDA ITEM # 13
Attachment #04.94
Request to establish a code for an automatic, self-adjusting sleep apnea breathing therapy device, trade name: DeVilbiss AutoAdjust LT.

Attachments:

- HCPCS Request summary sheets for each agenda item, including preliminary coding and payment recommendations.

- Memo to DME Public Meeting participants re: CMS' new, non-smoking campus policy.

- "Payment For Durable Medical Equipment" explanatory document, by Joel Kaiser, CMS.

- Procedures for Public Meetings For New Durable Medical Equipment (DME).

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 1, Attachment #04.82

Topic/Issue: Request to establish a code for devices providing Static Progressive Stretch ("SPS") Trade Name: Joint Active Systems, Inc. ("JCS").

Background/Discussion: Dean Kremer, of Joint Active Systems, Inc. has submitted a request to establish a code for an orthosis, limb brace, Trade Name: Joint Active Systems, Inc. ("JAS") Devices providing Static Progressive Stretch ("SPS"). According to the applicant, SPS is a therapeutic technique that incorporates a stress relaxation loading condition, defined as the reduction of forces over time in a material that is stretched and held at a constant length. SR is a loading condition that is effective in achieving permanent length changes in shortened connective tissue. It is the periodic, incremental application of SR loading forces throughout a treatment session. In the clinical setting, therapists routinely apply SPS to elongate shortened tissue by manually stretching a joint to end range and holding that position until relaxation occurs. SPS devices are designed mechanically to mimic clinical, manual SPS therapy. The JAS shoulder device provides SPS therapy for the treatment of restricted shoulder joint range of motion. Each JAS shoulder device is made up of two metal tower and two metal drive arms. Polypropylene, foam padded cuffs are attached to integral movable drive arms in the device. The cuffs are a single patient use item, and are sized and fitted specifically for the patient using the device. Range of motion adjustment knobs on the device are used to progressively increase the positional stretch applied to the joint tissues. Two range of motion knobs provide degree by degree adjustable SPS stretch in planes of external rotation (0-100 degrees) and abduction (20-120 degrees). The patient controls the degree of ROM and increases the stretch every five minutes over a thirty minute wearing protocol.

According to the applicant, the JAS shoulder was brought to market in July of 1998, elbow- 1992, knee- 1993, wrist- 1994, ankle- 1995, and pronation/supination- 1996. This item is used 98% of the time in the patient's home by the patient, 1% in nursing homes/skilled nursing facilities, and 1% in hospital outpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To establish a new "E" code.

E???? Multi-directional static progressive stretch shoulder device, with range of motion adjustability, includes cuffs.

Payment: Code E???? would fall under the capped rental payment category (HCPCS pricing indicator = 36). If covered, payment would be made on a rental basis. The rental fee schedule amounts would be gap-filled by the DMERCs.

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 2, Attachment #04.119

Topic/Issue: Request to establish 3 HCPCS codes for (1) portable overhead lifter, (2) portable track system, and (3) sling, trade name: Guardian Voyager.

Background/Discussion: Rita Hostak of Sunrise Medical submitted a request to establish 3 HCPCS codes for (1) portable overhead lifter, (2) portable track system, and (3) sling, trade name: Guardian Voyager System. According to the applicant, Guardian Voyager is designed to transfer patients that require the use of a lifter but the use of the more traditional floor lifter is not functional or may be hazardous to use. It has a lightweight design that allows for easy attachment to the Easytrack. The heavy-duty capacity is capable of handling patient weights up to 440 lbs. And the quick release strap prevents lifting the Voyager on the rail. A emergency stop safety feature and a lower strap twist prevention feature to help ensure patient and care-giver safety. Dual controls allow for easy access to controls to facilitate effortless up/down movement. The Easytrack allows usage in the smallest bedroom or anywhere a conventional floor lifter cannot be maneuvered. It's ceiling to floor spring-loaded design does not require permanent installation or alterations to the ceiling. Easytrack is available in a two post system, three post system or four post system.

According to the applicant, this product has been on the market since October 2001. This item is used 100% of the time in the patients' homes.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To discontinue code E0625 (patient lift, kartop, bathroom or toilet), because the Kartop product is no longer on the market, and establish a new "E" code.

E???? Patient lift, electric, with ceiling track system, portable or fixed.

Payment: This item is not covered because it does not meet the definition of durable medical equipment prescribed under the Medicare statute; therefore, no payment determination is necessary.

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 3, Attachment #04.122

Topic/Issue: Request to establish a code for a pneumatic compressor unit and various blanket attachments, that deliver heat, cold and compression to various injury sites trade name: ProThermo.

Background/Discussion: Debra Mills of Rheinisch Medical Management submitted a request to establish a code for a pneumatic compressor unit and various blanket attachments, trade name: ProThermo. According to the applicant, ProThermo is a control unit that delivers heat, cold and compression to injury sites through various blanket attachments. This device alternates between cold, hot and pneumatic modalities. ProThermo utilizes solid-state thermoelectric heat pumps that heat and cool with electricity. Exact temperature, compression, and contrast between heat and cold can all be directed with the control unit. There is also a contrast timing function for supervised treatment or overnight programming that can maintain exact temperature within one degree. Prothermo cools to reduce swelling; heats to promote warm-up and relax muscles; contrasts temperature for pain relief; and compresses for optimum performance. The blankets can also be used to apply wet or dry heat. Each feature is medically designed to speed up the body's natural healing process. Prothermo is used by athletes and post-surgical patients. The device is portable and can be set for an individual's need and then stored in memory for future therapy sessions. The blankets are made of polyurethane to remain flexible at any temperature, and are body-part-specific to effectively wrap the injury site. Channel velcro makes the blankets easy to adjust.

According to the applicant, this product has been on the market since April 2003. This item is used 30% of the time in physicians' offices, 65% in the patient's homes and 5% in physical therapy offices.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E1399 (durable medical equipment, miscellaneous) for the total system. It is inappropriate to use E0217, E0218, and E0650 for the purpose of billing Medicare. The HCPCS Workgroup would be happy to entertain another request when sales volume increases. There is no Medicare or Medicaid program operating need to institute a national code to identify this product.

Payment: If covered, claims for items billed using code E1399 (DME, Miscellaneous) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using E1399. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code E1399 is 46 for "carrier priced."

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 4, Attachment # 04.80

Topic/Issue: Request to establish a code for a pressure redistribution support surface, trade name: Tempur-Med Therapeutic Mattress.

Background/Discussion: Debra Harrington of Harrington Consulting submitted a request to establish a code for a pressure redistribution support surface, trade name: Tempur-Med Therapeutic Mattress. According to the applicant, this therapeutic support mattress consists of a mattress core having a therapeutic layer produced using a proprietary viscoelastic material, and a cover produced from materials compatible with the functionality of the core, known to address the microclimate needs of the skin. Tempur is made from a very dense, expanded, open-cell, urethane material. It has a relatively low hardness index and a glass-transition curve exhibiting selectivity in the range between body and room temperature. These factors result in the material delivering a controlled level of immersion and an extremely high degree of envelopment. The therapeutic value of the mattress is derived in large part from its ability to effectively reduce/eliminate peak pressure loading which is increasingly believed to be a primary factor in tissue ischemic as blood-flow is shunted away from these areas to areas where the resistance to blood-flow is lower. The cover of the Temur is manufactured using a high-performance, biocompatible urethane laminate. This fabric is stretchable, breathable, moisture impervious, and bacteriostatic. The basic fabric is very stable and has pronounced non-skid properties, minimizing the potential of the mattress to slide on the bed frame.

According to the applicant, this product has been on the market since 1992. This item is used 5% of the time in the patient's home 40% in nursing facilities and 55% in inpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E0184 dry pressure mattress. Insufficient substantiating, peer reviewed, clinical evidence of a difference in function or patient outcome as a result of use of this device.

Payment: Code E0184 falls under the payment category for inexpensive or routinely purchased items (HCPCS pricing indicator = 32). The national, purchase fee schedule ceiling for E0184 is currently $194.70 and the floor is $165.50. The national, monthly rental fee schedule ceiling for E0184 is currently $24.57 and the floor is $20.88.

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 5, Attachment #04.84

Topic/Issue: Request to establish a code for a chondrogenesis system, Trade Name: BioniCare® Stimulator, Model BIO- 1000™.

Background/Discussion: Tom Weiss, of BioniCare Medical Technologies, Inc., submitted a request to establish a code for a chondrogenesis system, Trade Name: BioniCare® Stimulator, Model BIO- 1000™. According to the applicant, the BioniCare® Stimulator, Model BIO-1000™ is used as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by a physician's global evaluation, and adjunctive therapy in reducing the level of pain and stiffness associated with pain from rheumatoid arthritis of the hand. The BioniCare system delivers a 0-12 volt, 100 Hz, monophasic negative electrical stimulus to the joint(s) and induces an electric current within cartilage. This stimuli has been shown to increase chondrocyte proliferation, DNA synthesis and new collagen and aggrecan formation of chondrocytes. The device is worn for 8 +/- hours every day. Clinical experience indicates that patients have used the device from 1 to 51 months, with the average being 11 months.

According to the applicant, this item was brought to market on August 1, 2003. This item is used 100% of the time in the patient's home by the patient.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E1399 (durable medical equipment, miscellaneous), due to low volume of documented use. Volume has not increased since their 1998 request. Insufficient peer reviewed clinical evidence to substantiate claim of chondrogenesis. There is no Medicare or Medicaid program operating need to institute a national code to identify this product.

Payment: If covered, claims for items billed using code E1399 (DME, Miscellaneous) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using E1399. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code E1399 is 46 for "carrier priced."

Attachment #04.85

Topic/Issue: Request to establish a code for replacement supplies for the BioniCare® Stimulator, Model BIO- 1000™.

Background/Discussion: Tom Weiss, of BioniCare Medical Technologies , Inc., submitted a request to establish a code for replacement supplies for a chondrogenesis system, Trade Name: Replacement Supplies for BioniCare® Stimulator, Model BIO- 1000™. According to the applicant, replacement supplies include contact elements/electrodes (2) and 8.5 oz. (250gm) supplementary gel tubes (6). This quantity of supplies is expected to last two to three months under typical product use conditions for one signal applicator. A second set of supplies would be required if a patient were using two signal applicators (bilaterally).

According to the applicant, this item was brought to the market on August 1, 2003. This item is used 100% of the time in the patient's home by the patient.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code A9999 (miscellaneous DME supply or accessory, not otherwise specified), due to low volume of documented use and insufficient peer reviewed clinical evidence of effect on humans or stimulation of cartilage repair. There is no Medicare or Medicaid program operating need to institute a national code to identify this product or its related replacement components.

Payment: If covered, claims for items billed using code A9999 (Miscellaneous DME Supply or Accessory) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using A9999. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code A9999 is 46 for "carrier priced."

Attachment #04.86

Topic/Issue: Request to establish a code for a replacement batter for the BioniCare® Stimulator, Model BIO- 1000™.

Background/Discussion: Tom Weiss, of BioniCare Medical Technologies, Inc., has submitted a request to establish a code for replacement batteries for a chondrogenesis system, Trade Name: Replacement Batteries for BioniCare® Stimulator, Model BIO- 1000™. According to the applicant, the rechargeable battery is required for continued operation of the electronic signal generator. Battery life is dependent on patient use patterns. Under normal use conditions, it is anticipated that a replacement battery will be required after 12 months.

According to the applicant, this item was brought to market on August 1, 2003. This item is used 100% of the time in the patient's home by the patient.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code A9999 miscellaneous DME supply or accessory, not otherwise specified.

Payment: If covered, claims for items billed using code A9999 (Miscellaneous DME Supply or Accessory) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using A9999. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code A9999 is 46 for "carrier priced."

Attachment #04.87

Topic/Issue: Request to establish a code for replacement supplies for a replacement Knee Signal Applicator for use with BioniCare® Stimulator, Model BIO- 1000™.

Background/Discussion: Tom Weiss, of BioniCare Medical Technologies, Inc., has submitted a request to establish a code for a chondrogenesis system, Trade Name: Knee signal applicator used with BioniCare® Stimulator, Model BIO- 1000™. According to the applicant, the knee signal applicator is used by patients with clinical indications specific to osteoarthritis of the knee. It delivers a specific electrical output to contact elements that are held in place by a knee signal applicator system that accurately positions and applies a special treatment contact element to the surface of the knee and a special return contact element to the surface of the thigh. The knee signal applicator is applied using a fastener system of Velcro materials, a support belt and suspension strap. They come in small, medium, and large. It is designed for use eight to ten hours per day for periods up to two years, and is designed to survive 350 hand-washing cycles. Each signal applicator is comprised of 25 components, including custom lamininated elastomer fabrics that are hand assembled in 21 separate positioning and sewing steps.

According to the applicant, this item was brought to market on August 1, 2003. This item is used 100% of the time in the patient's home by the patient.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code A9999 miscellaneous DME supply or accessory, not otherwise specified.

Payment: If covered, claims for items billed using code A9999 (Miscellaneous DME Supply or Accessory) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using A9999. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code A9999 is 46 for "carrier priced."

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 6, Attachment #04.96

Topic/Issue: Request to establish a code for a radiofrequency signal induction wound closure system, trade name: Provant® Wound Closure System.

Background/Discussion: Mary Ritz of Regenesis Biomedical, Inc. submitted a request to establish a code for a radiofrequency signal induction wound closure system, trade name: Provant® Wound Closure System. According to the applicant, Provant uses an advanced and highly specialized radiofrequency signal to induce the proliferation of fibroblasts and epithelial cells, which are key to the healing of wounds to full closure. These cell proliferation induction signals trigger the expression of an entire cascade of genes involved in the wound repair process and induce the release of numerous growth factors within the first few minutes of treatment. The effects of cell proliferation induction has been shown to accelerate the rate of expression of genes which are known to regulate all phases of wound repair and cell growth, including inflammation, colonization, second messenger activation, transcription, cell cycle activation, epithelialization, and remodeling. It also accelerates the rate at which specific cells go through the division process, including increasing the rate of DNA synthesis in fibroblasts by nearly two-fold and thereby accelerating proliferation. Provant is used to treat post surgical wounds that are unresponsive to standard therapies; non-healing or chronic diabetic, venous, arterial or pressure wounds of any size; and post-surgical wounds on a patient with history of difficult healing.

According to the applicant, this item was brought to the market late 1999. This item is used 35% of the time in patients home by patient, 10% in patients home by health care provider, 30% in nursing homes/skilled nursing facilities and 25% in hospital inpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: There is no Medicare or Medicaid program operating need to institute a national code to identify this product. The current volume of use does not justify the administrative burden of instituting a new national code. We will be happy to entertain another application once volume increases. In the meantime, use existing code E1399 (durable medial equipment, miscellaneous).

Payment: If covered, claims for items billed using code E1399 (DME, Miscellaneous) are paid in accordance with the fee schedule payment methodology; however, a fee schedule is not established for the HCPCS code because it is used for miscellaneous and varying items. The DMERCs establish local fee schedule amounts for groups of like items that are coded using E1399. The DMERCs will assign the items to a DME fee schedule category. The HCPCS pricing indicator for code E1399 is 46 for “carrier priced.”

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 7, Attachment #04.76

Topic/Issue: Request to establish a code for a cranial electrotherapy stimulation device, trade name: Alpha-Stim 100 and Alpha-Stim SCS.

Background/Discussion: Tracey Kirsch of Electromedical Products International, Inc. submitted a request to establish a code for cranial electrotherapy stimulation, trade name: Alpha-Stim 100 and Alpha-Stim SCS. According to the applicant, the Alpha-stim is used for the treatment of anxiety, depression, and insomnia. Cranial electrotherapy stimulation is the application of low levels of microcurrent stimulation applied transcutaneously to the brain for therapeutic purposes. Alpha stim is applied by clip-on electrodes that attach to the ear lobes. An electrode conducting solution is used to insure conductivity through the electrodes. Once the electrodes are moistened and applied, the device is turned on and the current is adjusted to where the patient feels a slight tingling sensation and then is reduced to where it is comfortable for the remainder of the treatment. The treatment is administered for 20 minutes to one hour depending on the current level, where sensitive people who prefer lower currents require more treatment time, anywhere from once a day to twice a week. Recommended dosage is 100-600 microamperes for 20 minutes to an hour, twice daily to as needed.

According to the applicant, this product has been on the market since October 1981. This item is used 9% of the time physician's offices, 2% in the patients' homes and 89% to distributors.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code A9270 non-covered item or service. Product is statutorily not covered by Medicare as per CIM 35-18. There is no need for a national code for Medicaid.

Payment: This item is not covered; therefore, no payment determination is necessary.

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 8, Attachment #04.70

Topic/Issue: Request for a code for a heated humidification system for ventilatory and respiratory assist applications, trade name: MR850 Heated Humidification System, a codes for the required system parts used in the initial patient set-up and as replacements.

Background/Discussion: Steve Moore of Fisher & Paykel Healthcare, Inc. submitted a request for a code for a heated humidification system for ventilatory and respiratory assist applications, trade name: MR850 Heated Humidification System, and additional codes to identify required system parts used in the initial patient set-up and as replacements. According to the applicant, its ultimate function is to deliver optimal humidity to the patient in a ventilatory or respiratory assist application. The MR850 humidification system is used during mechanical ventilation to condition the gas before being delivered to the patient. Gas must be conditioned to 37°C and contain 44mg/H20/ltr to maximize patient benefit. The MR850 is a new generation auto set dual servo controlled humidifier used in conjunction with volume ventilators, pressure control ventilators, and respiratory assist devices in the home. This system offers two modes of operation at the push of a button: invasive (trach) or non-invasive (mask) ventilation. The invasive mode is designed for use when the patient airway is bypassed and the noninvasive is used in mask ventilation with respiratory assist devices. MR850 humidification system is comprised of the heated humidifier based, a mounting bracket, a HC325 humidification chamber, a 72" heated wall breathing circuit, a 18" supply line tube, a 72" temperature/flow probe, an electrical adapter, and hose clips. Some of these components require replacement.

According to the applicant, this product has been on the market since July 2003. This item is used 30% of the time in the patient's home, 10% in nursing facilities and 60% in inpatient facilities.

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Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To revise E0562 which currently reads (humidifier, heated, used with positive airway pressure device), to instead read: Humidifier, heated, non-servo controlled, used with positive airway pressure device or ventilator.

and establish new "E" code:

E????Humidifier heated servo controlled, used with positive airway pressure device or ventilator.

Payment: Code E0562 falls under the payment category for inexpensive or routinely purchased items (HCPCS pricing indicator = 32). The national, purchase fee schedule ceiling for E0562 is currently $301.22 and the floor is $256.04. The national, monthly rental fee schedule ceiling for E0562 is currently $30.11 and the floor is $25.59. Code E???? would fall under the payment category for inexpensive or routinely purchased items (HCPCS pricing indicator = 32). If covered, payment would be made on a rental basis. The rental fee schedule amounts would be gap-filled by the DMERCs.

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 9, Attachment #04.77

Topic/Issue: Request to establish a code for a high flow humidification system, trade name: Vapotherm.

Background/Discussion: Bill Niland of Vapotherm, Inc. submitted a request to establish a code for a high flow humidification system, trade name: Vapotherm. According to the applicant, Vapotherm delivers breathing gas flows of up to 40 liters per minute directly to a nasal cannula, or other small tube respiratory interfaces. Vapotherm uses membrane transfer technology to saturate a stream of air and/or oxygen to generate a high flow of warm and sterile vapor. Vapotherm is used by patients with chronic lung diseases, acute respiratory insufficiency, apnea of prematurity, and respiratory compromise. The system consists of the base driver unit and a series of accessories for single patient use. The full Vapotherm system consists of the main processing unit, a flow source, a delivery tube and a high-flow cannula. In the main unit, compressed air or oxygen is taken from an oxygen source or a separate compressor and passed through a bacteriological filter. Then the air enters the vapor transfer cartridge, where it passes through tubes of membrane material surrounded by water at 33°C to 43°C. The membrane pore size of less than 0.015µ allows molecular water vapor to pass but retains bacteria and other particles, thereby eliminating the need for sterile water. This unique method produces a stream of air at 33°C to 43°C and 95-100% humidity at flow rates of up to 40 liters per minute. The hydronically heated deliver tube connects the main unit to a nasal cannula and is heated up to 43°C by warm water pumped from the main unit. The jacket of circulating warm water that represents the outer "lining" of the tube assures a condensate-free airstream delivered to the user's nasal cannula and into the patient's upper airway.

According to the applicant, this product has been on the market since 2003. This item is used 10% of the time in patient's home by the patient and 90% in hospital inpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E0550 humidifier, durable for extensive supplemental humidification during IPPB treatments or oxygen delivery. CMS HCPCS Workgroup requested literature to substantiate the clinical benefits of the therapy.

Payment: Code E0550 falls under the capped rental payment category (HCPCS pricing indicator = 36). The national, monthly rental fee schedule ceiling for E0550 for the first 3 rental months is currently $50.13 and the floor is $42.61. The rental fee schedule amounts for months 4 through 15 are reduced by 25 percent.

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 10, Attachment #04.72

Topic/Issue: Request to revise the description of code E0454 to include ventilators providing responsive triggering using other technologies in place of flow triggering, trade name: Newport HT50 Ventilator.

Background/Discussion: Amanda Bashant of Lash Group Healthcare Consultants submitted a request to revise the description of code E0454 to include ventilators providing responsive triggering using other technologies in place of flow triggering, trade name: Newport HT50 Ventilator. According to the applicant, the Newport HT50 is used for patients requiring intermittent and continuous mechanical ventilation. It can be used for patients weighing greater than 10kg or 22lbs, making the HT50 ideal for use in young children and adults. The HT50 contains micro-pistons that compress air for delivery to the patient. If needed, oxygen enrichment can be provided with either the optional low-flow blending bag kit or the optional 50psi air/oxygen entrainment mixer. The HT50 has three modes of operation: assist control mandatory positive pressure ventilation, synchronized intermittent mandatory ventilation, and spontaneous ventilation. All three modes have a choice of volume or pressure controls for mandatory breaths and pressure support for spontaneous breaths. The automatic slope/rise automatically adjusts flow delivery to the patient for every pressure control and pressure support breath and the built-in positive end-expiratory pressure (PEEP)/continuous positive airway pressure (CPAP) is servo controlled breath by breath. In addition, a comprehensive alarm system is built-in to alert the caregiver when violations of user-set and built-in safety limits occur.

According to the applicant, this product has been on the market since August 2000. This item is used 40% of the time in the patient's homes, 30% in nursing facilities, and 30% in inpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To discontinue E0454 (pressure ventilator with pressure control, pressure support and flow triggering features) to revise E0450 which currently reads (volume ventilator, stationary or portable, with backup rate feature, used with invasive interface (e.g. tracheostomy tube) to instead read: Volume control ventilator, without pressure support mode, may include pressure control mode, used with invasive interface (e.g. tracheal tube).

Revise E0461 which currently reads (volume ventilator, stationary or portable, with backup rate feature, used with non-invasive interface), to instead read: Volume control ventilator, without pressure support mode, may include pressure control mode, used with non-invasive interface (e.g. mask).

To establish the following "E" code:
E???1 Pressure support ventilator with volume control mode, may include pressure control mode, used with invasive interface (e.g. tracheal tube).

To establish the following "E" code:

E???2 Pressure support ventilator with volume control mode, may include pressure control mode, used with non-invasive interface (e.g. mask).

Use code E???1 or E???2 to describe the product, whichever is appropriate, depending on whether it is used with an invasive or non-invasive interface.

Payment: Proposed codes E???? and E???? would fall under the payment category for items requiring frequent and substantial servicing (HCPCS pricing indicator = 31). If covered, payment would be made on a rental basis. The rental fee schedule amounts would be gap-filled by the DMERCs.

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 11, Attachment #04.92

Topic/Issue: Request to establish a code for an automatic, self-adjusting sleep apnea breathing therapy device, trade name: AutoSet Spirit™ auto adjusting respiratory device.

Background/Discussion: Ron Richard of ResMed Corporation submitted a request to establish a code for a self-adjusting sleep apnea breathing therapy device, trade name: AutoSet Spirit™ auto adjusting respiratory device. According to the applicant, AutoSet Spirit is a flow-based auto-adjusting respiratory device used in the treatment of Obstructive Sleep Apnea. This device is only used when the patient has failed on a standard CPAP. Its mode of action delivers varying levels of pressures based on the detected sleep disordered breathing events and may change pressure on a breath-to-breath basis. This device responds to flow limitation, snoring, hypnopea, complete obstruction, or any combination of breathing patterns. AutoSet responds in a proactive fashion as it senses changes in flow and adjusts the pressure before the patient's airways begin to close thus preventing apnea and desaturation. It also allows for changes in pressure as a response to positional/sleep stage apneas, changes in upper airways, alcohol consumption, weight loss/gain and etc.

According to the applicant, this product has been on the market since July 2002. This item is used 90% of the time in the patients' homes and 10% in inpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E0601 (continuous airway pressure (CPAP) device) which adequately describes this product.

Payment: Code E0601 falls under the capped rental payment category (HCPCS pricing indicator = 36). The national, monthly rental fee schedule ceiling for E0601 for the first 3 rental months is currently $111.71 and the floor is $94.95. The rental fee schedule amounts for months 4 through 15 are reduced by 25 percent.

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 12, Attachment #04.93

Topic/Issue: Request to establish a code for an automatic, self-adjusting sleep apnea breathing therapy device, trade name: GoodKnight® 420 Evolution auto adjusting respiratory device.

Background/Discussion: Mary Erslon of Nellcor Puritan Bennett submitted a request to establish a code for a self-adjusting sleep apnea breathing therapy device, trade name: GoodKnight® auto adjusting respiratory device. According to the applicant, GoodKnight® is a flow-based auto-adjusting respiratory device used in the treatment of Obstructive Sleep Apnea. This device is only used when the patient has failed on a standard CPAP. Its mode of action delivers varying levels of pressures based on the detected sleep disordered breathing events and may change pressure on a breath-to-breath basis. This device responds to flow limitation, snoring, hypnopea, complete obstruction, or any combination of breathing patterns. GoodKnight responds in a proactive fashion as it senses changes in flow and adjusts the pressure before the patient's airways begin to close thus preventing apnea and desaturation. It also allows for changes in pressure as a response to positional/sleep stage apneas, changes in upper airways, alcohol consumption, weight loss/gain and etc.

According to the applicant, this product has been on the market since June 2003. This item is used 75% of the time in the patient's homes by the patients and 25% in the patient's homes by the health care provider.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E0601 (continuous airway pressure (CPAP) device) which adequately describes this product.

Payment: Code E0601 falls under the capped rental payment category (HCPCS pricing indicator = 36). The national, monthly rental fee schedule ceiling for E0601 for the first 3 rental months is currently $111.71 and the floor is $94.95. The rental fee schedule amounts for months 4 through 15 are reduced by 25 percent.

HCPCS REQUEST
June 30, 2004 Meeting Agenda Item # 13, Attachment #04.94

Topic/Issue: Request to establish a code for an automatic, self-adjusting sleep apnea breathing therapy device, trade name: DeVilbiss AutoAdjust LT.

Background/Discussion: Nicholas Macmillan of Sunrise Medical submitted a request to establish a code for a self-adjusting sleep apnea breathing therapy device, trade name: DeVilbiss AutoAdjust LT. According to the applicant, DeVilbiss offers automatic adjustment of air pressure by sensing air flow and compensating to meet the user's needs. It senses snoring and changes in breathing flow and continually adjusts CPAP pressures in relation to these changes. DeVilbiss increases CPAP pressures when snoring or specific breath flow patterns are detected, and decreases the CPAP pressure during periods of sleep when snoring or abnormal breath flows are not detected. The pressure profile changes are gradual to prevent arousals of sleep architecture, but are timely to respond to respiratory events requiring pressure adjustments. DeVilbiss contains a pneumotachometer which monitors the patient's airflow signal to identify any flow restrictions and snoring episodes associated with respiratory events. It is designed to minimize these flow restrictions. DeVilbiss also reduces airway pressure in an attempt to minimize the average supplied pressure administered throughout the night. These features keep the mean airway pressure at a minimum, resulting in the improvement of Obstructive sleep apnea therapy compliance and effective treatment of patients with highly variable pressure requirements due to state-dependent or positional sleep apnea.

According to the applicant, this product has been on the market since 1999. This item is used 90% of the time in the patients' homes and 10% in inpatient facilities.

Coding Recommendation: CMS HCPCS Workgroup preliminary recommendation to the HCPCS National Panel: To use existing code E0601 (continuous airway pressure (CPAP) device) which adequately describes this product.

Payment: Code E0601 falls under the capped rental payment category (HCPCS pricing indicator = 36). The national, monthly rental fee schedule ceiling for E0601 for the first 3 rental months is currently $111.71 and the floor is $94.95. The rental fee schedule amounts for months 4 through 15 are reduced by 25 percent.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-15
Baltimore, Maryland 21244-1850

Memorandum

TO: DME Public Meeting Participants

FROM: Jennifer Carver

DATE: June 8, 2004

SUBJECT: CMS' New, Non-Smoking Campus Policy

As the DME Public Meeting Coordinator, I have been asked to address all attendees of the DME Public Meetings regarding CMS' new policy making the entire CMS campus a non-smoking area.

Effective June 9, 2004, the entire Baltimore campus will be a non-smoking campus. This rule applies to all employees, contractors and visitors and includes all offices within the complex, parking facilities and any outside area that is part of the CMS single site campus. No one will be permitted to smoke within the CMS single site gated complex, including areas away from the doors or in vehicles parked in the complex. Those who violate the rule could face a fine as high as $50 that will be issued and enforced by the Federal Protective Service and/or be subject to disciplinary action, up to and including removal from the Federal service.

Thank you for your cooperation.

Jennifer Carver

PAYMENT FOR DURABLE MEDICAL EQUIPMENT (DME)

Section 1834(a) of the Social Security Act (the Act) requires that payment for DME furnished on or after January 1, 1989, be made on the basis of fee schedules. Prior to January 1, 1989, payment for DME was made on the basis of the reasonable charge methodology. For purposes of establishing the DME fee schedule, section 1834(a) of the Act separates DME into the following payment categories, each with its own unique payment rules:

- Inexpensive and other Routinely Purchased Items
- Frequently Serviced Items
- Oxygen and Oxygen Equipment
- Capped Rental Items

There is also a payment category for customized items. The carriers determine the payment amount for purchase of each customized item. These payment categories are described at the end of this document.

Section 1834(a) of the Act requires that statewide fee schedule amounts be established based on average reasonable charges made during a base period from 1986 to 1987, increased by 1.7 percent to arrive at 1989 ("base") fee schedule amounts. The specific months from 1986 to 1987 that are used to calculate the statewide fee schedule amounts vary by payment category. The fee schedule amounts are updated on an annual basis by a factor legislated by Congress. In addition, the fee schedule amounts are limited by a national ceiling (upper limit), equal to the median of the statewide fee schedule amounts, and a national floor (lower limit), equal to 85 percent of the median of the statewide fee schedule amounts.

Because reasonable charge data from 1986-87 does not exist for new DME items, the carriers must “gap-fill” the base fee schedule amounts for these items using a methodology provided in section 5101.2.A of the Medicare Carriers Manual. This section instructs the carriers to gap-fill using:

- the fee schedule amounts for comparable equipment,
- calculated fee schedule amounts from a neighboring carrier, or
- supplier price lists.

As a substitute for supplier price lists when they are not available, the carriers may gap-fill the base fee schedule amounts using the manufacturer's suggested retail prices or wholesale prices plus a markup.

The gap-filling methodology is used to approximate historic reasonable charges from 1986 to 1987 when historic data are not available. This gap-filling methodology has been in use since 1989, the initial year of the DME fee schedules. If neither reasonable charge data or prices lists from 1986-87 are available and more current prices are used, the carriers are instructed to decrease the more current prices by a "deflation" factor in order to approximate the 1986/1987 base year price for gap-filling purposes. The deflation factors are equal to the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the fee schedule base period (1986/87) to the mid-point of the year in which the retail price is in effect (e.g. 2001). After deflating the prices, the carriers will increase the prices by 1.7 percent to arrive at 1989 base fee schedule amounts.

The carriers then submit the 1989 base fee schedule amounts to CMS. To set the final fee schedule amounts, CMS applies all of the annual update factors that have occurred since 1989 to these base amounts and calculates the national ceiling and floor limits. The final fee schedule amounts are then transmitted to the carriers and fiscal intermediaries for implementation.

DME PAYMENT CATEGORIES

INEXPENSIVE AND OTHER ROUTINELY PURCHASED ITEMS
- Section 1834(a)(2) of the Act
- Fee Schedules: Purchase (new); Purchase (used); Rental (monthly)
- Fee Schedule Base Period: July 1, 1986 through June 30, 1987

Items that have a purchase price of $150 or less, are generally purchased 75 percent of the time or more, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or intermittent assist device with continuous airway pressure device. Total rental payments cannot exceed the purchase (new) fee for the item.

FREQUENTLY SERVICED ITEMS
- Section 1834(a)(3) of the Act
- Fee Schedules: Rental (monthly)
- Fee Schedule Base Period: July 1, 1986 through June 30, 1987

Items that require frequent and substantial servicing. Examples of such items are provided in section 1834(a)(3)(A) of the Act. These items are rented as long as they are medically necessary.

OXYGEN AND OXYGEN EQUIPMENT
- Section 1834(a)(5) of the Act

- Fee Schedules: Monthly Payment Amounts for Stationary Equipment, Oxygen Contents, Portable Oxygen Contents, and Portable Equipment
- Fee Schedule Base Period: January 1, 1986 through December 31, 1986

Monthly payments are made for furnishing oxygen and oxygen equipment. If the beneficiary owns their equipment, a monthly payment is made for oxygen contents only. An additional monthly payment is made for those beneficiaries who require portable oxygen. If the beneficiary owns their portable equipment, then a monthly payment is made for portable contents only.

CAPPED RENTAL ITEMS
- Section 1834(a)(7) of the Act
- Fee Schedules: Rental (monthly), Purchase (power wheelchairs only)
- Fee Schedule Base Period: July 1, 1986 through December 31, 1986

Payment for these items is on a rental basis. However, beneficiaries have the option to take over ownership of these items after the 13th rental payment. The supplier must inform the beneficiary of the "purchase option" in the 10th month of rental. If the beneficiary chooses the rental option, total rental payments may not exceed 15, but the supplier must continue to furnish the item as long as it is medically necessary.

The rental fee for capped rental items for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 15 is equal to 7.5 percent of the purchase fee for the item. Power wheelchairs can be purchased in the first month.

Beginning 6 months after the 15th rental payment is made, suppliers may be paid a semi-annual (every 6 months) maintenance and servicing fee that is not to exceed 10 percent of the purchase fee for the item. For patient owned items, payment for maintenance and servicing is made as needed.

CERTAIN CUSTOMIZED ITEMS
- Section 1834(a)(4) of the Act

Payment is made in a lump-sum amount for the purchase of the item in a payment amount based on the carrier's individual consideration for that item.

PROCEDURES FOR PUBLIC MEETINGS FOR NEW DURABLE MEDICAL EQUIPMENT (DME)

PURPOSE OF PUBLIC MEETINGS FOR NEW DME

The purpose of the DME Public Meetings is to provide a forum for the general public to present information regarding specific Healthcare Common Procedural Coding System (HCPCS) coding requests for new DME. The meeting also provides an opportunity to obtain industry and public reaction to the preliminary coding recommendations of the CMS HCPCS Workgroup to the HCPCS National Panel, as well as CMS' preliminary recommendations regarding payment methodology for new DME items. Public meetings are required for new DME, under Section 531(b) of the Benefits Improvement and Protection Act 2002 (BIPA). Coding decision related to the Medicare and Medicaid programs internal operating procedures are reviewed internally, and are not included in this forum.

ROLE OF THE PUBLIC MEETINGS FOR NEW DME, RELATIVE TO THE OVERALL HCPCS CODING PROCESS

The agenda for DME Public Meetings will consist of HCPCS coding requests for new DME, as determined by CMS, that have been submitted through the HCPCS coding review and recommendation process. The specific items on each public meeting agenda will be posted on the HCPCS web site at http://cms.hhs.gov/medicare/hcpcs/default.asp.

The DME public meetings are open to the public, including the Press, on a space-available basis. The meetings have typically been attended by representatives of medical equipment manufacturers and suppliers; government relations, regulatory and compliance specialist personnel from various provider organizations; industry consultants; and CMS staff. Entities who have an item on the public meeting agenda might attend, however their attendance is not mandatory.

The preliminary recommendations of the CMS HCPCS workgroup regarding coding requests, and CMS' preliminary payment methodology decisions, will be presented at the public meetings. After the public meeting, the CMS HCPCS workgroup will reconsider its preliminary coding recommendations, and CMS staff will reconsider its pricing recommendation, in view of information presented at the public meeting. The workgroup will formulate its recommendation to the HCPCS National Panel. No decisions are made at the DME Public Meetings. The National Panel is the entity that maintains the permanent HCPCS Level II codes, and is the final decision-making authority concerning requests for permanent HCPCS Level II codes. The DME Public Meetings are designed for DME manufacturers and others to present additional information, clarify issues, and offer supporting or opposing perspectives regarding CMS' preliminary decisions. Final coding decisions are not made at the public meetings, nor are they made by the HCPCS workgroup. Final payment decisions are made by CMS, in accordance with the Medicare Statute and regulations.

General information about the HCPCS coding process, the standard HCPCS code request form and instructions can be found on the official HCPCS web site at www.cms.hhs.gov/medicare/hcpcs/default.asp.

The official, update of the HCPCS code system is available as a Public Use File and can be downloaded for free at www.cms.hhs.gov/providers/pufdownload/anhcpcdl.asp

ADDITIONAL OPPORTUNITIES FOR PUBLIC INPUT

The National Panel Meeting Agenda, including all requests for permanent HCPCS Level II codes that have been submitted through the HCPCS coding review and recommendation process, are listed on the HCPCS web site at http://cms.hhs.gov/medicare/hcpcs/default.asp. Comments, recommendations and inquiries are welcomed, and may be submitted via e-mail to www.cms.hhs.gov/medicare/hcpcs or via regular mail to the HCPCS National Panel, c/o Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-08-27, Baltimore, Maryland 21244.

Comments and recommendations regarding items that appear on the Public Meeting Agenda for New DME may be made in person at the Public Meetings, and/or written comments may be provided at or prior to the meeting at the addresses noted above. Comments regarding Public meeting agenda items will be considered if they are received by the end of the meeting at which they are discussed.

MEETING LOCATION

DME Public Meetings are held in the Auditorium at the
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Meeting participants are responsible for arranging and funding their own travel and lodging.

NOTIFICATION OF PUBLIC MEETING, CONTENT OF THE AGENDA, AND MEETING SUMMARIES

Notice of Public Meetings for New DME appears in the Federal Register at www.access.gpo.gov/nara/index.html.

Public Meeting Dates, agendas and related materials, registration information and meeting summaries are published at http://cms.hhs.gov/medicare/hcpcs/default.asp. The agenda will be posted 2 to 4 weeks prior to the meeting. A meeting summary will be posted within one month after the meeting.

It is the responsibility of the applicant and the general public to monitor the appropriate web sites for announcements and other information related to the Public Meetings for New DME.

SELECTING AGENDA ITEMS FOR PUBLIC MEETINGS FOR NEW DME

Items are placed on a Public Meeting for New DME if:
The application for the item was complete and submitted timely to the National HCPCS process AND the item is considered by CMS to be new DME.

If you have submitted an application for a modification to the HCPCS system for an item you believe is DME, and your request is not represented on the agenda for the Public Meeting for New DME, please contact Joel Kaiser at 410-786-4499.

MEETING DATES AND TIMES, CALENDAR YEAR 2OO4

Tuesday, June 29, 2004
Wednesday, June 30, 2004

Each meeting day will begin at 9:00 a.m. and is scheduled to adjourn at 5:00 p.m., E.S.T. However, because it is impossible to anticipate whether all presentations will fill their allotted time period (e.g. 15 minutes for Primary Speakers; 5 minutes or "5-Minute Speakers"), we cannot commit specific items to specific time frames, and we can only estimate the amount of meeting time that will be needed. Meetings may end earlier than 5:00 p.m. Meeting participants should arrive early and plan on the meeting commencing promptly at 9:00 a.m., and speakers simply need to arrive prepared and wait until it is their turn to speak.

ON-LINE REGISTRATION CLOSES JUNE 18, 2004 FOR ALL PUBLIC MEETINGS IN CALENDAR YEAR 2004.

REGISTERING TO ATTEND A PUBLIC MEETING FOR NEW DME

Registration may be completed on-line at http://cms.hhs.gov/medicare /hcpcs/default.asp. If you do not have internet access you may contact the DME Public Meeting Coordinator, Jennifer Carver at 410-786-6610.

Upon completing on-line registration, you will automatically receive a confirmation. If you register by phone, a CMS staff member will confirm your registration by phone or fax. **Please bring your confirmation and government issued photo identification with you to the meeting,** (refer to Security information below).

On-line registration will not be accessible after June 18, 2004. Individuals who do not have internet access, or who have missed the deadline for on-line registration, may register by phone by contacting Jennifer Carver. The deadline for phone registration is June 22, 2003. Due to heightened national security, only registered individuals will be allowed to enter the building.

Pre-registration information is used to generate a list of attendees. The names of individuals who have pre-registered will appear on the attendee list. This list is used by Security guards to permit access into the building. It is also used to generate meeting sign-in sheets.

REGISTERING TO SPEAK AT A PUBLIC MEETING FOR NEW DME

Primary Speakers:

The entity that requested the modification to the HCPCS coding system for a particular agenda item may designate one "primary speaker" to make a presentation of a maximum of 15 minutes. Fifteen minutes is the total time interval for the presentation, and must incorporate the demonstration, set-up, and distribution of materials. In establishing the Public Meeting agenda, CMS may group multiple, related requests under the same agenda item. In that case, CMS will decide whether additional time will be allotted, and may opt to increase the amount of time allotted to the speaker by increments of less than 15 minutes. In other words, the amount of time allotted to aggregate proposals might not be expanded exponentially by the number of requests.

Primary Speaker Responsibilities:

- No later than 15 days in advance of the meeting:
    - Register to be a Primary speaker by personally notifying the DME Public Meeting Coordinator, Jennifer Carver at 410-786-6610.

- No later than 10 days in advance of the meeting:
    - Register on-line to attend the meeting.

- No later than 7 days in advance of the meeting:
    - Provide a brief, written statement to Jennifer Carver regarding the nature of the information that will be presented at the meeting.

    - In order to avoid disruption of the meeting and ensure compatibility with our systems, tapes and disk files are tested and arranged in speaker sequence in advance of the meeting. We will accommodate tapes and disk files that are received timely by the meeting coordinator.

    - Upon registering to be a Primary Speaker, indicate your needs for audio/video support. We offer an extensive array of audio and visual support options, (see below).

    AV Options:

    Audio Cassette Tape Playback
    Assisted Listening Device
    Video Tape playback (standard VHS or SVHS)
    DVD playback
    35mm slides (we can display slides through the projection system by use of a slide to video converter that is housed in the control room. Slides should be preloaded in Kodak-style carousel trays)
    Computer Display (compatible with CMS standard programs - check in advance with the meeting coordinator)

Computer Interface (we can interface the video projection system with most laptop computers equipped with a standard VGA output connector)
Document and/or overhead projector (overheads or hard copy pages can be projected from the control room)

- On the day of the meeting:
  - Primary speakers may bring handout materials with them, and distribute them at the meeting. Any materials distributed at the meeting should also be provided for review by the CMS HCPCS workgroup and the HCPCS National Panel. For that purpose, we request that at least 35 additional copies be provided, on the day of the meeting. Handout and demonstration materials may not be shipped in advance of the meeting.

  - Provide a written summary of your statement. State whether you support or disagree with the preliminary recommendation of the CMS HCPCS Workgroup and if you disagree, briefly summarize the reason(s) why.

  - All speakers must declare at the meeting as well as in their written summary whether or not they have any financial involvement with the manufacturers or competitors of any items or services being discussed. This includes any payment, salary, remuneration, or benefit provided to the speaker by the manufacturer.

<u>"5-Minute" Speakers:</u>

Meeting attendees will be permitted to sign up at the meeting, on a first-come, first-served basis, to make 5-minute presentations on individual agenda items. Based on the number of items on the agenda and the progress of the meeting, a determination will be made by the meeting coordinator and the meeting moderator, regarding how many 5-Minute speakers can be accommodated. In order to offer the same opportunity to all attendees, 5-Minute speakers may only register the day of the meeting, and not in advance of the meeting.

5-Minute speakers are required to submit, on the day of the meeting, a brief (one to two-page) summary of their presentation.

All speakers must declare at the meeting as well as in their written summary whether or not they have any financial involvement with the manufacturers or competitors of any items or services being discussed. This includes any payment, salary, remuneration, or benefit provided to the speaker by the manufacturer.

GUIDANCE TO SPEAKERS FOR AN EFFECTIVE PRESENTATION

We have established, based on experience, the following tips for an effective presentation:

<u>Information that is helpful:</u>

Begin with the preliminary recommendation itself, and comment on it. State your position. React specifically to the individual coding recommendation and either support or refute it. If you

disagree with the recommendation, provide substantiating information and explanation, and offer a recommendation as to how to correct it. Focus on factual information and objective, supporting documentation. Information that is in addition to that already provided in the application may help to make a point. The CMS HCPCS Workgroup has evaluated the requests that appear on the Public Meeting agenda, arrived at and published its preliminary coding recommendation. The Public Meeting forum is an opportunity to provide additional information that may convince the CMS HCPCS Workgroup to reconsider its preliminary recommendation, prior to releasing it to the HCPCS National Panel. Blanket dismissal of coding recommendation(s) or simply reiterating the original request without responding directly, and thoughtfully, to each individual preliminary coding recommendation does not help the workgroup to understand why the recommendation is unsatisfactory, or how or why it ought to be changed.

The focus of your presentation should be to convince the audience that your product fits the criteria for modifying the HCPCS coding system, as described in a document entitled "HCPCS BACKGROUND INFORMATION" at http://cms.hhs.gov/medicare/hcpcs/default.asp.

Describe who will and who will not benefit by the use of the item.

Information that is not helpful:

Keep in mind that HCPCS codes identify unique categories of products. The assignment of a HCPCS code does not guarantee, or even imply, that a product or service is covered by Medicare or by any other insurer. HCPCS decisions and coverage determinations are completely separate processes. Medicare coverage determinations are not part of the HCPCS coding decision-making process or part of the DME Public Meeting forum. Therefore, testimonials and discussions about medical necessity or efficacy are not beneficial, and may detract from the purpose of the meeting. It is inadvisable to expose at-risk patients for the purpose of providing testimony.

The Public Meetings for New DME are not directed to the attention of buyers of medical products. Therefore, promotional information, or a "sales pitch" that does not address uniqueness of the product category is inappropriate.

Timing of presentations:

Speakers may take less, but not more than the amount of time allotted (15 minutes for Primary Speakers, 5 minutes for "5-Minute" Speakers). Speakers may not give away, assign or yield unused time. Unused time is automatically forfeited to the moderator.

Only the moderator may call speakers. Speakers may not call other speakers.

In fairness to all speakers as well as to the audience, the moderator will end all presentations precisely at the end of their allotted time. Therefore, it is helpful to rehearse and time presentations so to ensure that key points are made within the allotted time.

The moderator reserves the right to interrupt to preserve the order of the meeting for the benefit of the audience.

WRITTEN COMMENTS FROM MEETING ATTENDEES

We welcome the written comments of other persons in attendance at the meeting, who did not have the opportunity to or did not care to make an oral presentation. These written comments must be submitted before the end of the meeting.

All speakers (Primary Speakers and 5-Minute Speakers) are required to submit, on the day of the meeting, a brief (one to two-page) summary of their presentation.

SPECIAL NEEDS

Persons attending the meeting who are hearing or visually impaired and have special requirements or a condition that requires special assistance or accommodations should make a notation to that effect on the registration form, or directly contact the DME Public Meeting Coordinator, Jennifer Carver, by the registration deadline at (410) 786-6610. Advance notice is necessary in order for us to make arrangements to accommodate special needs.

SECURITY ON THE DAY OF THE MEETING

All meeting attendees should bring with them government issued photo identification, and a copy of their pre-registration confirmation. The DME Public meetings are held in a government building; therefore, security measures will be applicable. Photo identification must be presented upon entering the complex and again upon signing-in at the security desk. Security Officers may deny access to the building complex to persons without proper identification. Meeting attendees must also provide registration information (confirmation of meeting registration). Meeting attendees should allow approximately 15 minutes to clear security upon arrival.

Any items brought to the building for the purpose of being demonstrated at the meeting must clear security. CMS does not assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety or security clearance of any belongings or items used for demonstration, or for their timely arrival at the meeting. We ask presenters to consider the practicality of bringing in large equipment or multiple pieces of equipment, and whether other means of demonstration, such as video or pictures, may be useful, less distracting, and much more easily managed.

In the event that the National Security level is elevated to code red please phone CMS at 410-786-6010. If the building is operating under a code red this means the building will be closed and the DME Public Meeting will be cancelled.

MEETING SIGN-IN ONCE ON-SITE

On-site sign-in for visitors who have pre-registered to attend the meeting will be held 30 minutes prior to the starting time of each meeting.

FAQ's

WHO MAY ATTEND DME PUBLIC MEETINGS?
The public, including the press, is invited to attend CMS' Public Meetings for New DME. Members of the CMS HCPCS Workgroup and CMS staff who have a special program interest in a topic may attend, based on their availability. Entities who submit requests that are being discussed at the meeting and their competitors might attend. Attendance at the Public Meetings for DME is voluntary and optional.

IS ATTENDANCE MANDATORY FOR ENTITIES WHO HAVE AN ITEM ON THE AGENDA?
No. Attendance is completely voluntary. Whether or not the requesting entity is represented at the meeting, all agenda items will be presented by CMS staff, with a description of the request and the preliminary recommendation of the CMS HCPCS Workgroup (as published with the agenda on the web).

ARE DECISIONS MADE AT THE PUBLIC MEETINGS FOR NEW DME?
No. The Public Meetings for New DME are not CMS HCPCS Workgroup meetings, and they are not HCPCS National Panel Meetings. The CMS' Public Meeting forum for New DME provides an opportunity for a requester to speak to CMS and to the Public, and an opportunity for CMS to hear from requester and public, and balance competing points of view. It is an opportunity for general public and competitors to participate in a discussion of HCPCS coding for New DME items.

Information provided at the CMS Public Meetings for New DME is shared with members of the CMS HCPCS Workgroup at a subsequent workgroup meeting. The workgroup reconsiders its preliminary recommendation in light of any new information provided, and formulates its recommendation to the HCPCS National Panel. The recommendation made by the CMS HCPCS work group to the HCPCS National may or may not be the same as the preliminary recommendation shared at the public meeting. The HCPCS National Panel may or may not agree with the recommendation of CMS HCPCS workgroup. The HCPCS National Panel is the final decision making authority concerning requests for permanent HCPCS Level II codes.

THE AGENDA DOES NOT INCLUDE TIMES. HOW DO PARTICIPANTS KNOW WHEN SPECIFIC ITEMS WILL BE DISCUSSED?
It is impossible to anticipate whether all presentations will fill their allotted time period (e.g., 15 minutes for Primary Speakers; 5 minutes for "5-Minute Speakers"), therefore we cannot commit specific items to specific time frames. We ask that speakers arrive prepared, plan on the meeting commencing promptly at 9:00 a.m, E.S.T., and simply wait until it is their turn to speak. Meetings are scheduled to adjourn at 5:00 p.m., however, because we can only estimate the amount of meeting time that will be needed, meetings may adjourn earlier than 5:00 p.m.

[Federal Register: April 23, 2004 (Volume 69, Number 79)]
[Notices]
[Page 22079-22080]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr23ap04-93]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1273-N]

Medicare Program; Public Meetings in Calendar Year 2004 for New Durable Medical Equipment Coding and Payment Determinations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meetings.

SUMMARY: This notice announces the dates and location of public meetings to be held in calendar year 2004 to discuss our preliminary coding and payment determinations for new durable medical equipment (DME). These meetings provide a forum for interested parties to make oral presentations or to submit written comments in response to preliminary coding and pricing recommendations for DME that have been submitted using the Healthcare Common Procedure Coding System coding modification process. Discussion is directed toward response to our specific preliminary recommendations, and will be limited to items on the new DME public meeting agenda.

DATES: The public meetings are scheduled for Tuesday, June 29; Wednesday, June 30; and Thursday, July 1, 2004. Each meeting day will begin at 9 a.m. and end at 5 p.m., e.d.t. A meeting will only be held on July 1, 2004, if the number of agenda items cannot be managed in two meeting days.

ADDRESSES: The public meetings will be held in the Centers for Medicare & Medicaid Services (CMS) Auditorium, located at 7500 Security Boulevard, Baltimore, MD 21244.

Web site: Additional details regarding the public meeting process for new DME, along with information on how to register and guidelines for an effective presentation, will be posted at least one month before the first meeting date on the official HCPCS Web site, and can be accessed at http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://cms.hhs.gov/medicare/hcpcs/default.asp.

Individuals who intend to provide a presentation at a public meeting for new DME need to familiarize themselves with this information. This Web site also includes a description of the HCPCS coding process, along with a detailed explanation of the procedures used to make coding and payment determinations for DME and other items

and services that are coded in the HCPCS.

A summary of each public meeting for new DME will be posted on the above Web site within one month after the meeting.

FOR FURTHER INFORMATION CONTACT: Jennifer Carver, (410) 786-6610.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Public Law 106-554. Section 531(b) of BIPA mandated that we establish procedures that permit public consultation for coding and payment determinations for new DME under Medicare Part B of title XVIII of the Social Security Act (the Act). The procedures and public meetings announced in this notice for new DME are in response to the mandate of section 531(b) of BIPA.

We published a notice in the November 23, 2001, Federal Register (66 FR 58743) with information regarding the establishment of the public meeting process for DME.

II. Registration

Registration Procedures: Registration may be completed online at http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://cms.hhs.gov/medicare/hcpcs/default.asp, or you may contact the

DME Public Meeting Coordinator, Jennifer Carver at 410-786-6610, to register by phone. The following information must be provided when registering: Name, company name and address, telephone and fax numbers, e-mail address and special needs information. Registrants must also indicate whether they are the ``Primary Speaker'' for an agenda item, designated by the entity that submitted the HCPCS coding request. A CMS staff member will confirm your registration by mail, e-mail or fax.

Registration Deadline: Individuals must register for each date they plan to attend and/or provide a presentation. The deadline for registration for all of the meetings dates is Tuesday, June 15, 2004.

III. Presentations and Comment Format

A. Primary Speaker Presentations

The entity that submitted the HCPCS coding request for an item that appears on the Public Meeting agenda may designate one person to be the ``Primary Speaker'' and make a presentation at the meeting. We will post guidelines regarding the amount of time allotted to the speaker, as well as other presentation guidelines, on the official HCPCS website at least a month before the first public meeting in 2004 for new DME. Persons designated to be a Primary Speaker must register to attend the meeting using the registration procedures described above and, at least 15 days before the meeting, contact the DME Public Meeting Coordinator, Jennifer Carver at 410-786-6610. At the time of registration, Primary Speakers must provide a brief, written statement regarding the nature of the information they intend to provide, and advise the meeting coordinator regarding needs for Audio/Visual Support. In order to avoid

disruption of the meeting and ensure compatibility with our systems, tapes and disk files are tested and arranged in speaker sequence well in advance of the meeting. We will accommodate tapes and disk files that are received by the DME Public Meeting Coordinator 7 or

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more calendar days before the meeting. In addition, on the day of the meeting, Primary Speakers must provide a written summary of their comments to the DME Public Meeting Coordinator.

B. ``5-Minute'' Speaker Presentations

Meeting attendees will be permitted to sign up at the meeting, on a first-come, first-served basis, to make 5-Minute presentations on individual agenda items. Based on the number of items on the agenda and the progress of the meeting, a determination will be made at the meeting by the meeting coordinator and the meeting moderator, regarding how many 5-Minute speakers can be accommodated. In order to offer the same opportunity to all attendees, there is no pre-registration for 5-Minute speakers. Attendees may signup only on the day of the meeting to do a 5-Minute presentation. They must provide their name, company name and address, contact information as specified on the sign-up sheet, and identify the specific agenda item that will be addressed. On the day of the meeting, 5-Minute speakers must provide a written summary of their comments to the DME Public Meeting Coordinator.

C. Speaker Declaration

The Primary Speakers and the 5-Minute Speakers must declare, at the meeting as well as in their written summary, whether or not they have any financial involvement with the manufacturers or competitors of any items or services being discussed. This includes any payment, salary, remuneration, or benefit provided to the speaker by the manufacturer.

D. Written Comments from Meeting Attendees

We welcome written comments from persons in attendance at a public meeting, whether or not they had the opportunity to make an oral presentation. Written comments may be submitted at the meeting, or prior to the meeting via e-mail to http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.cms.hhs.gov/medicare/hcpcs or

via regular mail to the HCPCS Coordinator, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-08-27, Baltimore, MD 21244.

IV. General Information

The meetings are held in a Federal government building; therefore, Federal measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. In order to gain access to the building and grounds, participants must bring a government-issued photo identification and a copy of your confirmation of pre-registration for the meeting. Access may be denied to persons without proper identification.

Security measures also include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection. CMS cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation.

Special Accommodations: Persons attending a meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance or accommodations, must provide this information upon registering for the meeting.

Each meeting day will begin at 9 a.m. and end at 5 p.m., e.d.t. Because it is impossible to anticipate, in advance of the April 1, 2004, submission deadline, the nature and the number of coding requests that will be submitted for new DME, we can only estimate the amount of meeting time that will be needed, and we are unable to post a final agenda at this time. We may not need three full-day meetings. We will consider each meeting individually, and we may modify the meeting dates and times published in this notice. Final confirmation of meeting dates and times, and agenda items will be posted three weeks in advance of each scheduled meeting, on the official HCPCS Web site and can be accessed at http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://cms.hhs.gov/medicare/hcpcs/default.asp.

Authority: Section 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 42 U.S.C. 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: March 25, 2004.
Dennis G. Smith,
Acting Administrator, Centers for Medicare & Medicaid Services.
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